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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,284	01/29/2001	Samuel Nochumson	260/243	2969
25746	7590	12/02/2004	EXAMINER	
WONG CABELLO LUTSCH RUTHERFORD & BRUCCULERI, LLP			OWENS JR, HOWARD V	
20333 SH 249, SUITE 600				
HOUSTON, TX 77070			ART UNIT	PAPER NUMBER
1623				
DATE MAILED: 12/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/774,284	NOCHUMSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Howard V Owens	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 August 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 104 and 109-114 is/are pending in the application.
- 4a) Of the above claim(s) 115-121 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 104 and 109-121 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/13/04</u> .	6) <input type="checkbox"/> Other: _____

***Response to Arguments***

The following is in response to the amendment filed 8/9/04:

An action on the merits of claims 104 and 109-114 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Newly added claims 115-121 withdrawn**

Newly submitted claims 115 - 121 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 115 to 121 are drawn to a method of purifying contaminants from plasmid DNA via tentacle anion exchange chromatography, wherein the claims originally presented were drawn to the use of precipitation to remove the contaminants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 115 – 121 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the

subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 104 and 109 – 114 are rejected under 35 U.S.C. § 103 as being unpatentable over Wan et al., U.S. Patent No. 5,837, 529 in combination with Kasai, J. of Chromatography, Vol. 618, pp. 203-21, 1993 and Koller et al., J. Chromatography B Biomed. Appl., vol. 664(1), pp. 107-118, 1995.

Claims 104 and 109-114 have been amended to include the use TMAE chromatography to distinguish the claims over the prior art of record. Applicant claims that TMAE was not indicated in the use of processing DNA prior to applicant's invention. Wan teaches a method for lysing cells using a dual line feed of cell suspension and lysing solution to a primary static mixer; wherein the lysate is fed to a secondary static mixer with a precipitating solution fed separately to the secondary static mixer. Wan anticipates the dependent claims as it further teaches a flow rate of 1 L/min. (col.4, line 18), use of a non acidic unbuffered salt solution in the form of acetate or chloride (col.3, line 50), basic lysis solution (col. 3, lines 19-21), wherein the precipitate comprising contaminants consisting of RNA, chromosomal DNA, lipids and protein, col. 3- col.4).

Wan however does not teach the use of the anion exchange and hydrophobic interaction columns in the purification of plasmid DNA. Kasai bridges the nexus between the prior art and the instant claims as it teaches the use of anion exchange and hydrophobic interaction columns in the separation of nucleic acids. Moreover, the use of tentacle anion exchange chromatography had been used in the prior art as demonstrated by Koller wherein the TMAE was used in the purification of DNA which bridges the nexus between the prior art and the invention as claimed.

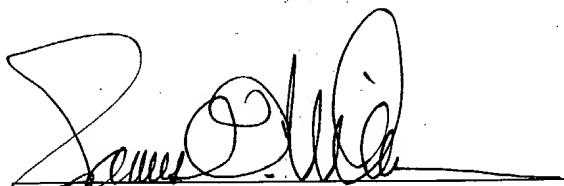
It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use anion exchange chromatography or hydrophobic interaction column chromatography in the purification of plasmid DNA.

A person of ordinary skill in the art would have been motivated to use anion exchange and hydrophobic interaction columns given the established use of these columns in the prior art for the separation and purification of nucleic acids.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Howard V. Owens  
Patent Examiner  
Art Unit 1623



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

Art Unit: 1623

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.